were used. Of these, 27 studies used telephone and text reminders. Four used educational materials and books while another four used blister packing. Three studies used interactive voice response system, two studies used letters and faxes, and another two studies used pill boxes. Improvement in medication adherence was found in all studies. The largest change in medication adherence was observed through the use of telephone and text reminders. **CONCLUSIONS:** Medication adherence is a problem that pharmacists are addressing through health care reform legislation. It's important for pharmacists/researchers to educate about effective adherence tools in order to improve quality of care to patients and society.

PRM164

THE CORRELATION BETWEEN PATIENT REPORT OUTCOMES AND CLINICIAN REPORTED OUTCOMES

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OBJECTIVES: To explore evidence of the degree of correlation between patient reported outcomes (PROs) and clinician reported outcomes (ClinROs), and how this varies by therapeutic area, measure and language. **METHODS:** A review of the literature and analysis of existing patient registry data was conducted to qualitatively assess degree of correlation between PROs and ClinROs – at points in time, change over time, and how the relationship between these assessments varies by disease area and measure. A review of translation and linguistic validation projects involving PRO and ClinROs was also conducted to examine language-related differences and correlations between the scales. Specific examples of PRO-ClinRO pairs are given for multiple sclerosis, rheumatoid arthritis, and atopic eczema, among others. **RESULTS:** For multiple sclerosis and rheumatoid arthritis, moderate correlation (0.5-0.7) was found between patient assessments of disease severity and physician assessment, with patient assessments influenced by concomitant feelings (e.g., depression, anxiety). The correlation between patient and clinician assessment of change/responsiveness depends on whether an improvement or deterioration is experienced, where deterioration has a perceived stronger impact, patient-wise, than an improvement. Differences in language complexity and terminology between PROs and ClinROs were essential for the appropriate comprehension by the target population. Clinically appropriate and current terminology used for ClinROs was key to clinicians accepting the scale as relevant. Simple, clear phrasing and wording with language with lower education level was important for PROs. **CONCLUSIONS:** For reviewing PROs and ClinROs, specific differences in language and terminology must be taken into account, both in the development of instruments and linguistic validation into various target languages. In some disease areas, a significant and strong correlation of patient's assessment with objective clinical measures may support its use as a valid proxy measure of clinical status, thus opening up multiple research design opportunities where the perspective of the patient is paramount.

PRM165

EXPLORING THE HUMANISTIC AND ECONOMIC BURDEN OF CROHN'S DISEASE: CONSIDERATIONS FOR NOVEL COMPOUNDS

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OBJECTIVES: Crohn's disease (CD) is an inflammatory bowel disease affecting approximately 1.4 million people in the United States. The aims of this study were to document current unmet needs in CD in terms of patient-reported and economic burden; and how such concepts may be assessed to capture the overall benefit of new CD therapies for patients, health care systems and society. **METHODS:** Articles were identified in MEDLINE, EMBASE, EconLit, HEED, CRD databases and PSYCINFO using pre-defined search terms/limits. 561 abstracts were identified; and 31 full articles were reviewed. Direct and indirect costs of CD were extracted as were patient-relevant concepts (symptoms and impacts) to form a patient-relevant conceptual model. Patient-reported measures were identified in PROQOLID and were assessed in context of FDA guidance. **RESULTS:** CD symptoms manifest primarily as gastrointestinal disturbances including abdominal pain/cramping and diarrhoea. Fever, fatigue and weight loss are also prominent symptoms. These symptoms impact patients' physical functioning, daily activities, emotional well-being, and ability to work. Seven patient-reported measures were reviewed in-depth; measures of HRQoL (IBDQ, SF-36, IBDQOL), occupational functioning (CPWDQ, WPAI:CD) and disease activity/symptoms (CDAI, CDAI-short, GSRS). Instruments to assess HRQoL and occupational functioning used concurrently with the CDAI may demonstrate the wider influence of treatment on other symptoms and patients' lives. CD is associated with substantial direct costs, estimated at $18-$19,000 per-patient per-year in the US, and indirect costs, estimated at $7,260 per-patient per-year. Costs are especially high in sub-groups (e.g. presence of fistulas). **CONCLUSIONS:** The disease course of CD is characterised by remissions and relapses, thus lifetime humanistic and economic burden is substantial. This review highlights the need for disease-specific patient-reported measures that provide comprehensive assessment of relevant domains of disease activity/symptoms, HRQoL and occupational functioning. Further research into drivers of direct and indirect costs of CD is necessary to meet cost-effectiveness requirements.

PRM166

PATIENT-REPORTED OUTCOMES IN FDA-APPROVED PRODUCT LABELS: RECENT TRENDS AND METHODS FOR ASSESSING SUCCESSFUL INCLUSION OF PROS

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OBJECTIVES: The FDA approved 39 new molecular entities (NMEs) in 2012, and many efficacy claims were supported by patient-reported measures or statements. In addition, many previously-approved products were approved for a new indication supported by PRO endpoints in recent years. The purpose of our research was to conduct an in-depth analysis of recently approved claims supported by PROs in order to identify notable trends, and to describe best methods for assessing the success rate of PRO inclusion. **METHODS:** Published FDA product labels, literature and Internet searches were utilized. All labels of NMEs and new indications approved by the FDA from 2010 to 2012 were reviewed. A measure or statement of efficacy was considered to be a PRO if it assessed symptoms, reduced side effects, or impacts on functioning from the patient's perspective. **RESULTS:** There were 21, 30, and 39 NMEs approved in 2010, 2011, and 2012. In these years, 12, 19, and 13 NME labels contained PRO-related claims or statements (67%, 63%, 33%), and pain-related PROs were the most common (n's=4, 11, 8). Cumulative distribution function (CDF) graphs were present in 13 NME labels during these years. Importantly, from 2010 to 2012 many products added indications with efficacy claims supported by a PRO, but such a submission was not considered an NME (e.g., pregabalin). From 2006 to 2009, PRO-related claims were included in 66% of approved NMEs. This rate decreased to 49% during 2010 – 2012; however, more PRO claims (44 versus 50; 2010-2012) are revealed when reviewing more than NMEs. **CONCLUSIONS:** Development, testing, and validation of PRO measures as clinical trial endpoints remain important for facilitating the approval of drugs and communicating value to the consumer. Reviewing NDA and BLA labels is a more accurate assessment of the success of PRO inclusions in FDA-approved labels than reviewing NMEs alone.

PRM167

PREDICTING MEDICATION ADHERENCE USING RETAIL PHARMACY DATA

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OBJECTIVES: Apply data mining techniques to pharmacy data to identify patients likely to be non-adherent to their medication in the next six months. **METHODS:** Catalina Health™ receives a nationally representative sample of pharmacy data containing 40% of all U.S. retail prescription volume and 130 million unique patient ID's. The data is HIPAA compliant, longitudinal, and not projected. Select 7 prescription medications representing multiple therapeutic classes. For each medication, randomly select a 100K patient cohort filling a prescription between June and August 2010. In order to eliminate patients who switch pharmacies or migrate to mail order, exclude patients who have no history of filling any drug during the prior 18 months, or who have no fill history for any drug during the six month analysis period. Fit logistic regression models to predict which patients will be non-adherent to their medication in the next six months. Consider patients non-adherent when Proportion of Days Covered (PDC)<80%. Model covariates include prior adherence to the medication (if applicable), adherence for co-morbid conditions, days supply of the medication, ethnicity and income variables, patient age and gender, paid with cash, number of refills remaining, medication dose, and number of co-morbidities. Model accuracy is assessed using a 20% hold-out of the data. **RESULTS:** The models identified 40.3% of the patients as likely to be non-adherent to their medication in the next six months. This varied by medication (23.2% - 64.6%) and patient type (28.8% Experienced, 38.9% Moderate Experienced, and 77.5% New). The overall model accuracy rate is 70.4%. 72.3% of the patients predicted to be non-adherent were actually non-adherent (precision), while 69.1% of the patients predicted to be adherent were actually adherent. **CONCLUSIONS:** Data mining techniques applied to pharmacy data can predict patients who are likely to be non-adherent to their medication in the next six months with 72.3% precision.

PRM168

DEVELOPMENT OF THE ANGINA PATIENT SELF-MANAGEMENT QUESTIONNAIRE

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OBJECTIVES: Guidelines had present many management recommendations to physicians on angina prevention and treatment. However patients still knew less about angina management in China. They need Heart education. Thus, we want to develop an angina patient self-management questionnaire (ASMQ). **METHODS:** We hypothesized the questionnaire should carry messages of risk factors, prevention and treatment of angina. Items were determined from guidelines, and interview of patients and cardiovascular doctors. A five point Likert scale was chosed as the response format. Higher score means better management. The questionnaire was tested along with a cross-sectional angina study. Reliability was evaluated via internal consistency, and test-retest reliability. Construct validity was tested through Exploratory Factor Analysis (EFA), and discriminant validity was assessed by detecting differences between in-patients and out-patients. We assumed in-patients learn more about angina than out-patients. **RESULTS:** The ASMQ contained 12 items organized in two domains: risk-factor and self-management. The ASMQ was tested on 430 patients (age 63±12 year; 171 male, 40%); Of those, 150 (35%) were outpatients, and 86 (20%) retested 24 hours later. Test-rest correlation coefficient of the ASMQ was 0.740, and 0.719, 0.780 for risk-factor and self-management domains respectively. Cronbach's alpha coefficient was 0.616 of the overall questionnaire, and 0.692 of the self-management domain. But the risk-factor domain was 0.432, showed an unsatisfied internal consistency. Three factors were extracted through EFA, and were stratified into 2 domains as expected. The score of in-patients (43±7) was higher than out-patients (41±6), which showed a better management among in-patients (p=0.017). **CONCLUSIONS:** The ASMQ showed an